CLAIMS

1. A male contraceptive formulation comprising an effective amount of a progestin, wherein said progestin possesses both androgenic and estrogenic properties.

2. A formulation according to claim 1, wherein the progestin is norethisterone (NET), or its derivatives, such as its carboxylic esters, in particular its acetate or enanthate.

3. A formulation according to claim 1, wherein levels of said progestin are sufficient to suppress spermatogenesis.

4. A formulation according to claim 1, wherein levels of said progestin are sufficient to induce oligozoospermia or azoospermia.

5. A formulation according to claim 2, wherein the dose of the NET derivative is between 1 and 10 mg, such as 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 mg.

6. A formulation according to claim 2, wherein the dose of the NET derivative corresponds to a dose of 100-500 mg for each 6-week administration, particularly between 200 and 400 mg for each 6-week administration.

7. A formulation according to claim 1 comprising progestin in sufficient amounts to lower the Pearl-index to not more than 1.4, such as not more than 1.2, 1.0. 0.8, 0.7. 0.6, 0.5, 0.4, 0.3, 0.2, or 0.1.

8. A formulation according to claim 1 comprising progestin in sufficient amounts to lower the sperm concentration to not more than 3 million/ mL, such as not more than 2 million/ mL, 1 million/ mL, 0.5 million/ mL, 0.25 million/ mL, or not more than 0.1 million/ mL.

9. A formulation according to claim 1 comprising progestin in sufficient amounts to lower the sperm concentration to not more than 0.1 million/ mL.

10. A formulation according to claim 1, wherein the effective levels are sustained for not less than 1 week, such as not less than 2, 3, 4, 5, 6, 7,8, 9, 10, 11, or 12 weeks.

11. A formulation according to ~~any of the preceding claims~~ claim 1 for non-oral administration.

12. A formulation according to claim 11, adapted to be administered via intramuscular injection, intravenous injection, subcutaneous implantation, subcutaneous injection or transdermal preparation.

13. A male contraceptive formulation comprising an effective amount of a progestin, wherein said progestin possesses both androgenic and estrogenic properties and further comprising in one composition an androgen wherein said formulation is for non-oral administration.

14. A male contraceptive formulation comprising an effective amount of a progestin, wherein said progestin possesses both androgenic and estrogenic properties and further comprising in a non-identical composition an androgen wherein said formulation is for non-oral administration.

15. A formulation according to ~~any of claims 13 or 14,~~ claim 13 wherein the progestin is norethisterone (NET), or its derivatives, such as its esters, in particular its acetate or enanthate ester, particularly its enanthate ester.

16. A formulation according to ~~any of claims 13 or 14,~~ claim 13 wherein the androgen is testosterone or its derivatives, such as an ester, such as testosterone 17-undecanoate.

17. A formulation according to ~~any of claims 13 or 14,~~ claim 13 wherein the amount of androgen is sufficient to not observe peripheral symptoms associated with androgen deficiency.

18. A formulation according to ~~any of claims 13 or 14~~ claim 13, comprising a combination of NET or derivatives thereof and the androgen in sufficient amounts to suppress spermatogenesis.

19. A formulation according to claim 13 ~~or 14~~, comprising NET or derivatives thereof and the androgen in sufficient amounts to lower the Pearl-index to not more than 1.4, such as not more than 1.2, 1.0. 0.8, 0.7. 0.6, 0.5, 0.4, 0.3, 0.2, or 0.1.

20. A formulation according to ~~any of claims 13 or 14~~ claim 13, comprising NET and derivatives thereof and the androgen in sufficient amounts to lower the sperm concentration to not

more than 3 million/ mL, such as not more than 2 million/ mL, 1 million/ mL, 0.5 million/ mL, 0.25 million/ mL, or not more than 0.1 million/ mL.

21. A formulation according claim 20, comprising NET and derivatives thereof and the androgen in sufficient amounts to lower the sperm concentration to not more than 0.1 million/ mL.

22. A formulation according to ~~any of claims 13, or 14~~ claim 13, wherein the effective levels are sustained for not less than 1 week.

23. A formulation according to claim 22, wherein the effective level of NET and derivatives thereof and the androgen are sustained for not less than 2 weeks.

24. A formulation according to claim 23, wherein the effective level of NET and derivatives thereof and the androgen are sustained for not less than 4 weeks.

25. A formulation according to claim 24, wherein the effective level of NET and derivatives thereof and the androgen are sustained for not less than 6 weeks between administrations.

26. A formulation according to claim 24, wherein the effective level of NET and derivatives thereof and the androgen are sustained for not less than 8 weeks.

27. A formulation according to claim 26, wherein the effective level of NET and derivatives thereof and the androgen are sustained for not less than 10 weeks.

28. A formulation according to claim 27, wherein the effective level of NET and derivatives thereof and the androgen are sustained for not less than 12 weeks.

29. A formulation according to ~~any of claims 13 to 28~~ claim 13 adapted to be administered via intramuscular injection, intravenous injection, subcutaneous implantation, subcutaneous injection and transdermal preparations.

30. A formulation according to ~~any of claims 13 to 28,~~ claim 13 wherein the methods of administrations of the progestin are selected from the group consisting of intramuscular

injection, intravenous injection, subcutaneous implantation, subcutaneous injection and transdermal preparations and the methods of administrations of the androgen are selected from the group consisting of oral administration, intramuscular injection, intravenous injection, subcutaneous implantation, subcutaneous injection and transdermal preparation.

31 A formulation according to claim 30, wherein the methods of administration are selected from the group comprising subcutaneous implants and transdermal patches.

32. A formulation according to claim 30, wherein the dose of the NET derivative corresponds to a daily release of the NET ester ranging between 1 and 10 mg.

33. A formulation according to claim 30, wherein the dose of the NET derivative ranges between 100 and 500 mg for each 6 week administration.

34. A formulation according to claim 30, wherein the dose of the NET derivative ranges between 150 and 250 mg for each 6 week administration.

35. A formulation according to ~~any of claims 32 to 34~~ claim 33, wherein the NET derivative is selected from NET enanthate and NET acetate.

36. A formulation according to claim 30, wherein the dose of the testosterone derivative corresponds to a daily release of testosterone in amounts ranging between 5 and 35 mg.

37. A formulation according to claim 36, wherein the dose of the testosterone derivative corresponds to the daily dose of testosterone ranging between 15 and 30 mg.

38. A formulation according to claim 30, wherein the dose of the testosterone derivative corresponds to a dose of testosterone ranges between 500 and 1200 mg for each 6 week administration.

39. A formulation according to claim 38, wherein the dose of the testosterone derivative corresponds to a dose of testosterone of 800 mg for each 6 week application.

40. A formulation according to claim 16, wherein the dose of the testosterone undecanoate is between 800 and 1500 mg for each 6 week administration.

41. A formulation according to claim 40, wherein the dose of the testosterone undecanoate is 1000 mg for each 6 week administration.

42. The use of NET, or derivatives thereof, for the preparation of a pharmaceutical composition for use as a male contraceptive.

43. The use of a combination of NET, or derivatives thereof, and an androgen for the preparation of a pharmaceutical composition for use as a male contraceptive.

44. The use of a combination of a NET ester and testosterone or derivative thereof for the preparation of a pharmaceutical composition for use as a male contraceptive.

45. A use according to claim 43, wherein the androgen is a testosterone ester.

46. A use according to claim 43, wherein the androgen is a testosterone undecanoate.

47. A use according to claim 42 ~~or 43~~, wherein the NET derivative is NET enanthate or NET acetate.

48. A use according to claim 47, wherein the NET derivative is NET enanthate.

49. The use of NET enanthate and testosterone undecanoate for the preparation of a pharmaceutical composition for use as a male contraceptive.

50. A method of providing male contraception comprising administering to an individual NET or a derivative thereof in an amount sufficient to suppress spermatogenesis.

51. A method according to claim 50, comprising administering a non-oral formulation.

52. A method of providing male contraception comprising administering to an individual a combination of NET or a derivative thereof and an androgen as a non-oral formulation in an amount sufficient to suppress spermatogenesis.

53. A method according to claim 52, wherein the androgen is testosterone or a derivative thereof.

54. A method according to claim 53, wherein the androgen is a testosterone ester.

55. A method according to claim 54, wherein the androgen is testosterone undecanoate.

56. A method of providing male contraception comprising administering to an individual a combination of NET acetate and testosterone undecanoate as a non-oral formulation in an amount sufficient to suppress spermatogenesis.